

REMARKS

This paper responds to the Office Action dated February 9, 2005. Claims 33, 36, and 39 are amended; as a result, claims 22-33 and 35-43 are pending in this application.

§112 Rejection of the Claims

Claims 26-28, 30 and 32 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicant respectfully traverses the rejection.

Claim 26 recites in part, wherein detecting the error in a change includes detecting a non-programmer initiated change from the first state of the one or more programmable parameters to the second state. The Office Action asserts that the subject matter not described are the different ways to detect an error in a change. The specification discloses on page 10 lines 16-21 that if one or more of the parameter values and/or states are not within acceptable ranges, one or more programs contained within the electronic circuitry of the implantable pulse generator attempt to correct the error(s). The specification also refers generally to a microprocessor based architecture (or other logic based architecture) executing a program, and a memory circuit that includes parameters including states (*see e.g.*, page 13 line 24 through page 14 line 6). The specification further describes reviewing changes by retrieving the log (*see* page 6 lines 16-18). Applicant respectfully submits that the specification, at least in the examples shown, does indeed describe ways to detect errors in a change, either by using the logic-based device or by review of the retrieved log, and shows that Applicant was in possession of the subject matter of claim 26 at the time the application was filed and does not include new subject matter.

Claim 27 recites wherein detecting the error in a change includes detecting a change in state associated with an expiration of energy supplied by a battery in the implantable pulse generator. The specification discloses that the state of the one or more programmable parameters is changed from a first state to a second state by the exhaustion of the power supply to the implantable pulse generator, that the implantable pulse generator ceases to operate when the

energy supply from the battery expires, and that the termination of the executable program and/or the deactivation of the implantable pulse generator is recorded in the parameter log (*see* page 8 lines 16-26). The specification on page 10 lines 16-21 describes the device detecting that one or more of the parameter values and/or states are not within acceptable ranges and the implantable pulse generator attempts to correct the error(s). The specification also describes reviewing changes by retrieving the log (*see* page 6 lines 16-18). Applicant respectfully submits that the specification, at least in the examples shown, describes ways to detect errors in a change in state associated with an expiration of energy supplied by a battery, and shows that Applicant was in possession of the subject matter of claim 27 at the time the application was filed and does not include new subject matter.

Claim 28 recites wherein detecting the error in a change includes detecting execution of an electronic circuitry reset program. The specification discloses that the state of the one or more programmable parameters is changed from a first state to a second state by the execution of an electronic circuitry reset program stored in the implantable pulse generator, and that the execution of the electronic circuitry reset program is recorded in the parameter log (*see* page 9 lines 1- 6). The specification on page 10 lines 16-21 describes the device detecting that one or more of the parameter values and/or states are not within acceptable ranges and the implantable pulse generator attempts to correct the error(s). The specification also describes reviewing changes by retrieving the log (*see* page 6 lines 16-18). Applicant respectfully submits that the specification, at least in the examples shown, describes ways to detect errors in execution of an electronic circuitry reset program, and shows that Applicant was in possession of the subject matter of claim 28 at the time the application was filed and does not include new subject matter.

Claim 30 recites wherein detecting the error in a change includes detecting use of a magnetic signal to control operation of the implantable pulse generator. The specification discloses where the use of a magnetic signal to disable the operation of the implantable medical device is logged in the implantable pulse generator (*see, e.g.,* page 7 lines 3-5, and page 10 line 24 through page 11 line 4). The specification describes the device detecting that one or more of the parameter values and/or states are not within acceptable ranges (*see* page 10 lines 16-21). The specification also describes reviewing changes by retrieving the log (*see* page 6 lines 16-18). Applicant respectfully submits that the specification, at least in the examples shown, describes

detecting errors that includes detecting use of a magnetic signal, and shows that Applicant was in possession of the subject matter of claim 30 at the time the application was filed and does not include new subject matter.

Claim 32 recites wherein detecting the error in a change includes detecting a change due to an influence external to the implantable pulse generator. The specification discloses where the first state of the implantable medical device is changed due to an external influence, factor and/or signal, and that this later influencing signal has the effect of changing the operation of the implantable from the first state to a second state (see page 5 lines 8-15). The specification further describes signals originating from a medical device programmer and from a magnet initiating changes that are stored in a log (*see, e.g.,* page 6 lines 21 through page 7 line 5). The specification also describes providing information in a log that determines how the change occurred, and describes the device detecting that one or more of the parameter values and/or states are not within acceptable ranges (*see* page 10 lines 16-21). Applicant respectfully submits that the specification, at least in the examples shown, describes detecting errors in a change due to an influence external to the implantable pulse generator, and shows that Applicant was in possession of the subject matter of claim 32 at the time the application was filed and does not include new subject matter.

Based on the above and the specification as a whole, applicant respectfully requests reconsideration of the 35 U.S.C. § 112, first paragraph and allowance of claims 26-28, 30 and 32.

Claims 23, 26-30 and 32 were rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written enablement requirement. The Office asserts the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is it most nearly connected, to make and/or use the invention. Applicant respectfully traverses the rejection.

Claim 23 recites wherein detecting the error in a change includes detecting one of an error in a deactivation of the executable program and an error in an activation of the executable program. The specification describes logging deactivation of an executable program (*see, e.g.,* page 8 lines 14-15, and lines 25-26) and activation of an executable program (*see, e.g.,* page 6 lines 6-9, page 8 lines 4-6). The specification describes deactivation due to events including magnetic signal activation and reset, and to logging such events (*see, e.g.,* page 7 lines 3-5 and

page 9 lines 4-7). The specification also refers generally to a microprocessor based architecture (or other logic based architecture) executing a program, and a memory circuit that includes parameters including states (*see e.g.*, page 13 line 24 through page 14 line 6). The specification further describes reviewing changes by retrieving the log (*see* page 6 lines 16-18). Thus, because the specification describes logging changes in activation states and logging events such as magnet activation, one of ordinary skill in the art would understand that conflicting log entries would be an error detectable either by using the logic-based device or by review of the retrieved log, and therefore the description in the specification enables one skilled in the art to make and/or use the invention.

Claim 26 recites in part, wherein detecting the error in a change includes detecting a non-programmer initiated change from the first state of the one or more programmable parameters to the second state. The specification discloses on page 10 lines 16-21 that if one or more of the parameter values and/or states are not within acceptable ranges, one or more programs contained within the electronic circuitry of the implantable pulse generator attempt to correct the error(s). The specification also refers generally to a microprocessor based architecture (or other logic based architecture) executing a program, and a memory circuit that includes parameters including states (*see e.g.*, page 13 line 24 through page 14 line 6). The specification further describes reviewing changes by retrieving the log (*see* page 6 lines 16-18). Applicant respectfully submits that because the specification describes determining whether a value or state stored in a memory circuit is an acceptable one, either by using a program executing on a microprocessor or by review of the retrieved log, the description in the specification enables one skilled in the art to make and/or use the invention.

Claim 27 recites wherein detecting the error in a change includes detecting a change in state associated with an expiration of energy supplied by a battery in the implantable pulse generator. The specification discloses that the state of the one or more programmable parameters is changed from a first state to a second state by the exhaustion of the power supply to the implantable pulse generator, that the implantable pulse generator ceases to operate when the energy supply from the battery expires, and that the termination of the executable program and/or the deactivation of the implantable pulse generator is recorded in the parameter log (*see* page 8 lines 16-26). The specification on page 10 lines 16-21 describes the device detecting that

one or more of the parameter values and/or states are not within acceptable ranges and the implantable pulse generator attempts to correct the error(s). The specification also describes reviewing changes by retrieving the log (see page 6 lines 16-18). Thus, because the specification discloses detecting that a state of a parameter is in error and that deactivation occurred, either by using the device or by review of the retrieved log, the description in the specification enables one skilled in the art to make and/or use the invention.

Claim 28 recites wherein detecting the error in a change includes detecting execution of an electronic circuitry reset program. The specification discloses that the state of the one or more programmable parameters is changed from a first state to a second state by the execution of an electronic circuitry reset program stored in the implantable pulse generator, and that the execution of the electronic circuitry reset program is recorded in the parameter log (*see* page 9 lines 1- 6). The specification on page 10 lines 16-21 describes the device detecting that one or more of the parameter values and/or states are not within acceptable ranges and the implantable pulse generator attempts to correct the error(s). The specification also describes reviewing changes by retrieving the log (see page 6 lines 16-18). Thus, because the specification discloses that the device is capable of detecting that a state of a parameter is in error and of detecting that a reset program was executed, either by using the microprocessor-based device or by review of the retrieved log, the description in the specification enables one skilled in the art to make and/or use the invention.

Claim 29 recites wherein detecting the error in a change includes detecting termination of the executable program. The specification describes logging termination and deactivation of an executable program (*see*, e.g., page 5 lines 12-15, and page 8 lines 14-15). The specification also describes reviewing changes by retrieving the log (see page 6 lines 16-18). The specification describes deactivation and termination due to events including magnetic signal activation, battery malfunction, and reset, and to logging such events (*see*, e.g., page 2 lines 21-26, page 7 lines 3-5, and page 9 lines 4-7). Thus, because the specification describes logging changes in activation states and logging events such as magnet activation, one of ordinary skill in the art would understand that conflicting log entries, detected by either the device or by review of the retrieved log, would be an error, and therefore the description in the specification enables one skilled in the art to make and/or use the invention.

Claim 30 recites wherein detecting the error in a change includes detecting use of a magnetic signal to control operation of the implantable pulse generator. The specification discloses where the use of a magnetic signal to disable the operation of the implantable medical device is logged in the implantable pulse generator (*see, e.g.,* page 7 lines 3-5, and page 10 line 24 through page 11 line 4). The specification describes the device detecting that one or more of the parameter values and/or states are not within acceptable ranges (*see* page 10 lines 16-21). The specification also describes reviewing changes by retrieving the log (*see* page 6 lines 16-18). Thus, because the specification discloses detecting that a state of a parameter is in error and that a magnet signal disabled the device, either by using the device or by review of the retrieved log, the description in the specification enables one skilled in the art to make and/or use the invention.

Claim 32 recites wherein detecting the error in a change includes detecting a change due to an influence external to the implantable pulse generator. The specification describes where the first state of the implantable medical device is changed due to an external influence, factor and/or signal, and that this later influencing signal has the effect of changing the operation of the implantable from the first state to a second state (*see* page 5 lines 8-15). The specification further describes signals originating from a medical device programmer and from a magnet initiating changes that are stored in a log (*see, e.g.,* page 6 lines 21 through page 7 line 5). The specification also describes providing information in a log that determines how the change occurred, and describes the device detecting that one or more of the parameter values and/or states are not within acceptable ranges (*see* page 10 lines 16-21). The specification further describes reviewing changes by retrieving the log (*see* page 6 lines 16-18). Thus, because the specification describes detecting errors in a change by either using the device or by reviewing the retrieved log, that the change can be made from external influences including a programmer and a magnet, and that the log stores how changes were made, the description in the specification enables one skilled in the art to make and/or use the invention.

Based on the above and the specification as a whole, applicant respectfully requests reconsideration and allowance of claims 23, 26-30 and 32.

Allowable Subject Matter

Applicant acknowledges the allowance of claims 22, 24, 25, 31, 42 and 43.

Request for Reentry of Withdrawn Claims

Amended claims 33, 36 and 39 are base claims that were previously withdrawn. Applicant respectfully submits that the base claims in their present form and their dependent claims are species claims to generic claim 42. Applicant respectfully requests that claims 33, 35-41 be reentered for examination.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 349-9587 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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11 April '05

By

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